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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,080	01/07/2002	Michel Coste	B45171	9246

20462 7590 06/16/2004

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EXAMINER

HUYNH, PHUONG N

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/914,080	<b>Applicant(s)</b> COSTE ET AL.	
	<b>Examiner</b> Phuong Huynh	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2001.
- 2a) ☐ This action is **FINAL**.      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 21-40 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

- I. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
- II. Claims 21-40 are pending.

### *Election/Restrictions*

- III. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:
- This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:
1. Claims 22-24, and 29-34, drawn to an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the **peptide is IgE epitope** or mimotope thereof.
  2. Claims 22-24, 27-28, and 30-34, drawn to an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the peptide is **Gonadotrophin hormone** releasing hormone or mimotope thereof.
  3. Claims 22-26, and 30-34, drawn to an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the peptide is a fragment of the **amyloid precursor protein** or mimotope thereof.
  4. Claims 35-36, drawn to a method manufacturing an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the peptide is IgE epitope or mimotope thereof.
  5. Claims 35-36, drawn to a method manufacturing an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the peptide is Gonadotrophin hormone releasing hormone or mimotope thereof.

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6. Claims 35-36, drawn to a method manufacturing an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the peptide is a fragment of the amyloid precursor protein or mimotope thereof.
7. Claims 37-40, drawn to a method of treating a specific chronic or a specific infectious disease comprising administering a vaccine comprising an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the peptide is IgE epitope or mimotope thereof.
8. Claims 37-40, drawn to a method of treating a specific chronic or a specific infectious disease comprising administering a vaccine comprising an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the peptide is a fragment of the amyloid precursor protein or mimotope thereof.
9. Claims 37-40, drawn to a method of treating a specific chronic or a specific infectious disease comprising administering a vaccine comprising an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenzae or a fragment thereof as a carrier wherein the peptide is a fragment of the amyloid precursor protein or mimotope thereof.

The inventions listed as Groups 1-9 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The EP 0263655 publication teaches a peptide such as n-X-Arg-Val-His-Pro-His-Leu-Pro-Arg-Ala-Leu-Met-Arg-Ser-Thr-Thr-Lys-Thr-Ser-Gly-Pro-Arg-Ala-Ala-Pro-Glu-Val-Tyr-Ala-Phe-Ala-THr-Pro-Glu-Trp-Pro-Gly (See page 3, line 50-56, in particular) comprising an Cε2-Cε4 domains of human IgE and mimotope thereof wherein the reference peptide is useful for treating allergy (See page 4, line 44-45, page 3, line 1-2, page 5, lines 46-50, claims of EP 0263655, in particular). The EP 0263655 publication further teaches various IgE peptides (mimotope) such as the ones recited in claims 1-17 of the EP 0263655 publication. The EP 0263655 publication teaches a pharmaceutical composition comprising the reference peptide or

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mimotope and a carrier molecule such as sterile saline solution for immunization (injection) (page 5, lines 1-2, in particular).

The claimed invention as recited in claim 21 differs from the references only by the recitation that the carrier molecule is Protein D.

The EP 0594610 B1 publication teaches Protein D which is an Ig receptor for human IgD that recognized the surface exposed protein from all strains of Haemophilus Influenzae (See entire document, column 3, line 20, in particular) and fusion protein comprising any polypeptide fused to Protein for a vaccine (See column 4, lines 1-15, Claim 13 of EP 0,594,610 B1, in particular). The reference Protein D is a valuable with other molecules such as proteins and polysaccharides in the stimulation of the immune system through an interaction with B-lymphocytes (See column 2, lines 12-16, in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to conjugate the IgE peptide fragments or mimotopes as taught by the EP 0263655 publication to the protein D from Haemophilus as taught by the EP 0594610 B1 publication for an immunogen comprising a peptide coupled to Protein D from Haemophilus Influenza wherein the peptide is between 2-50 amino acid residues in length. From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable of success in producing the claimed invention. One having ordinary skill in the art at the time the invention was made would have been motivated to do this because the EP 0263655 publication teaches a peptide such as n-X-Arg-Val-His-Pro-His-Leu-Pro-Arg-Ala-Leu-Met-Arg-Ser-Thr-Thr-Lys-Thr-Ser-Gly-Pro-Arg-Ala-Ala-Pro-Glu-Val-Tyr-Ala-Phe-Ala-THr-Pro-Glu-Trp-Pro-Gly (See page 3, line 50-56, in particular) comprising an Cε2-Cε4 domains of human IgE and mimotope thereof is useful for treating allergy (See page 4, line 44-45, page 3, line 1-2, page 5, lines 46-50, claims of EP 0263655, in particular).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

Linking claim 21 will be examined along with the elected Group if any one of Group 1-3 is elected.

- IV. Accordingly, Groups 1-9 are not so linked as to form a single general inventive concept and restriction is proper.

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V. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

VI. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VII. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone

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are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.  
The IFW official Fax number is (703) 872-9306.

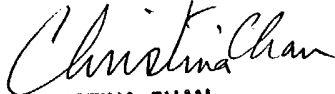
VIII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

June 10, 2004

  
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